

January 4, 2005

Jo Anne B. Barnhart, Commissioner of Social Security
P.O. Box 17703
Baltimore, Maryland 21235-7703

RE: Revised Medical Criteria for Evaluating Impairments of the Digestive System,
Chronic Liver Disease

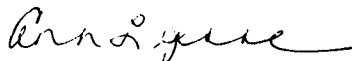
Dear Commissioner Barnhart,

Hep C Connection, a national, nonprofit advocacy organization, is happy to hear that you are considering revised medical criteria for evaluating impairments of the digestive system detailed in the notice of proposed rulemaking (NPRM) published in the Federal Register on November 14, 2001 (66 FR 57009). Our support and information network is in contact with hundreds of individuals living with hepatitis C and struggling with the physical, financial, and emotional devastation that this epidemic produces. We submit our comments in response to the reopening of the comment period as published in the Federal Register on November 8, 2004 (69 FR 64702).

As a member of the National Hepatitis C Advocacy Council, we have had an opportunity to review the recommendations (attached) proposed by the Hepatitis C Caring Ambassadors Program, an organization which participated in the SSA Policy Conference on Chronic Liver Disease held in Cambridge, Massachusetts. We feel that these recommendations are comprehensive, well researched, and indicate an impressive understanding of the medical criteria related to chronic liver disease and specifically, to hepatitis C. Hep C Connection strongly encourages SSA to take these recommendations under serious consideration.

Please contact me if you would like any additional information. Thank you for your willingness to examine these very important issues.

Sincerely,



Ann Jesse, Executive Director

**Comments Submitted by
The Hepatitis C Caring Ambassadors Program
to the Social Security Administration**

**PROPOSED REVISED MEDICAL CRITERIA
FOR EVALUATING CHRONIC LIVER DISEASE**

I. CHRONIC LIVER DISEASE AND CHRONIC HEPATITIS C IN THE UNITED STATES

Chronic liver disease ranks among the top ten causes of death for all Americans age 25-74 years. It is the 4th leading cause of death among those 45-54 years, 6th among those 35-44 years, and 7th for those 55-64 years.¹ Hepatitis C disease is the most common cause of chronic liver disease in the U.S., accounting for approximately 40-60% of all cases.²² Furthermore, hepatitis C-related disease is the leading indication for liver transplantation. Thus, consideration of chronic liver disease and its associated morbidity and mortality must focus on the most common cause of such disease, chronic hepatitis C.

The third National Health and Nutrition Examination Survey (NHANES III, 1988-1994) conducted by the Centers for Disease Control and Prevention (CDC) documented that at least 3.9 million Americans have been infected with the hepatitis C virus (HCV), and at least 2.7 million have chronic infection. Given the exclusion of specific high-risk populations from the study sample, the actual prevalence is probably substantially higher than estimated by NHANES III. One study estimates that up to 5 million in the U.S. are infected with HCV.³ Those age 30-39 years at the time of the NHANES III survey had the highest prevalence rate and accounted for 65% of all persons with detectable anti-HCV.⁴ Clearly, the American workforce is substantively impacted by the current hepatitis C epidemic.

RECOMMENDATION 1

HCV-related disease is the most common cause of chronic liver disease in the U.S. and as such should be directly addressed by SSA in the medical criteria for evaluating chronic liver disease.

II. THE CHRONIC HEPATITIS C DISEASE SPECTRUM

Fifty-five to 85% of people exposed to HCV become chronically infected.^{5,6} Over a 20-year period, approximately 20-30% of people with CHC develop cirrhosis. Ten percent of those with cirrhosis eventually progress to end-stage liver disease and/or develop hepatocellular carcinoma. Coinfection with HIV and/or the hepatitis B virus, and ongoing alcohol consumption accelerate HCV-related disease progression.^{7,8,9}

Most people with chronic hepatitis C (CHC) have initially clinically quiescent disease that causes little to no impairment in terms of quality of life and productivity. However, a significant

portion of those with CHC develop significant impairment due to hepatic and/or extrahepatic manifestations of the disease. Although the hepatitis C virus is primarily a hepatotropic virus, chronic hepatitis C is a systemic disease and can cause a myriad of constitutional and organ-specific symptoms. An abbreviated list HCV-related symptoms includes:

cognitive dysfunction	recurrent fevers	abdominal pain & bloating
fatigue	musculoskeletal pain	diarrhea
mood and sleep	nausea and dyspepsia	constipation
disturbances	appetite disturbances	intractable pruritus

HCV has been isolated from the brain tissue of infected patients, a finding that suggests central nervous system involvement of the virus.^{10, 11} At least 50% of people with chronic hepatitis C experience cognitive impairment and fatigue, both of which may lead to significant disability. Importantly, these impairments have been documented even among patients without cirrhotic changes in the liver.^{12, 13, 14, 15, 16, 17, 18} Therefore, histologic diagnosis is insufficient to evaluate cognitive and constitutional disability among patients with chronic hepatitis C. Neuropsychiatric and psychosocial testing with established, standard instruments are essential for evaluating these impairments.

People with chronic hepatitis C commonly suffer from a variety of extrahepatic manifestations of hepatitis C-related disease including, but not limited to:

- insulin resistance and glucose abnormalities
- cryoglobulinemia
- membranoproliferative glomerulonephritis
- thyroiditis
- porphyria cutanea tarda
- polyarteritis nodosum
- Sjögren's syndrome
- peripheral neuropathy
- arthritis-like joint pain
- secondary complications of cirrhosis
 - spontaneous bacterial peritonitis and/or recurrent infections
 - electrolyte and acid/base imbalances
 - coagulopathy
 - hepatopulmonary syndrome
 - hepatic osteodystrophy

The frequency with which extrahepatic manifestations are experienced as a result of chronic hepatitis C necessitates that they be taken into account and directly factored into the medical evaluation of chronic liver disease. Further, chronic liver disease evaluation criteria should address the constellation of signs and symptoms present in an individual rather than focusing on one or two criteria that may or may not be reliable indicators of disability.

Intractable pruritus warrants special mention because of the severity and relative frequency of this symptom among people with chronic liver disease. This symptom is experienced as unrelenting and continuous itching that is often experienced over large areas of the body. This

symptom often causes prolonged insomnia, agitation, secondary skin infections, disfigurement, depression, and not infrequently, suicidal ideation and execution of such ideation. Treatment-resistant, intractable pruritus with associated complications should be a listing level disability for anyone with documented chronic liver disease.

RECOMMENDATION 2

Histologic diagnosis is insufficient to evaluate cognitive and constitutional disability among patients with chronic hepatitis C. Neuropsychiatric and psychosocial assessment with established, standard methods or instruments is essential for evaluating these impairments.

RECOMMENDATION 3

Evaluation criteria must allow for the assessment of potentially debilitating and common extrahepatic manifestations of chronic hepatitis C disease.

III. PROPOSED MEDICAL EVALUATION CRITERIA FOR CHRONIC LIVER DISEASE WITH RECOMMENDATIONS FOR REVISION

We have reviewed the proposed changes to the aforementioned evaluation criteria, and have the following specific comments and recommendations, which are limited to the adult criteria. Overall, we believe the proposed medical evaluation criteria are exceedingly narrow, and in places, are inconsistent with the natural history and pathophysiology of chronic liver disease. More specific comments and rationale are noted with each recommended change; comments and recommendations are noted in bold blue text.

RECOMMENDATION 4

Revise the proposed medical evaluation criteria for chronic liver disease to more accurately address the epidemiology, natural history, and pathophysiology of chronic liver disease in the U.S.

Introductory Text

A. *What kind of impairments do we consider in the digestive system?*

No comments or recommendations on the proposed changes.

B. *What documentation do we need?*

1. When we assess gastrointestinal or liver impairments, we usually need longitudinal evidence covering a period of at least 6 months of observations and treatment, unless we can make a fully favorable determination or decision without it. **For example, evidence of irreversible liver failure and/or complications of portal hypertension that are progressive in nature would not require a 6 month observation period since the likelihood of substantial improvement with these conditions is negligible and the**

prognosis is usually one of progressive impairment. The evidence should include all available clinical and laboratory findings, including appropriate medically acceptable imaging studies, endoscopy, operative and pathology reports, **and assessments of quality of life and functional cognitive impairments.** Criteria for documentation will be found in the individual listings.

C. How do we evaluate digestive disorders under listings that require recurring or persistent findings?

NOTE: We believe the 6 and 12 month requirements discussed in this section are medically inappropriate for many people who have progressed to decompensated cirrhosis. The timeframe during which a patient with compensated cirrhosis transitions to decompensated cirrhosis is usually prolonged. However once this threshold has been crossed, continued deterioration is expected. In a person with demonstrable decompensated cirrhosis, these requirements are unnecessary and medically inappropriate since the overall prognosis in such cases is one of progressive deterioration.

Similarly, the 3 events within a consecutive 6 month period with 1 month between events requirement is medically inconsistent with the natural history of chronic liver disease. While certain complications of chronic liver disease (especially those complications that arise from portal hypertension) tend to be episodic, the natural history of chronic liver disease is as its moniker suggests, chronically progressive. Thus episodic requirements alone are inappropriate for the medical evaluation of such conditions. Furthermore, the periodicity noted in this section appears somewhat arbitrary rather than based on sound gastroenterological knowledge. For example, massive ascites requiring paracentesis may be required more frequently than monthly, depending on the rate of reaccumulation and comorbidities. While those people requiring frequent paracentesis are clearly more ill than those requiring less frequent paracentesis, the proposed criteria would negate this reality among this extremely ill population.

D. How do we consider the effects of treatment?

No comments or recommendations on the proposed changes.

E. How do we evaluate impairments that do not meet one of the digestive listings?

1. These listings are only examples of common digestive impairments that we consider severe enough For example, when liver disease results in hepatic encephalopathy, we should evaluate the impairment(s) under the criteria for the appropriate mental disorder or neurological listing(s).

NOTE: We submit that evaluation of hepatic encephalopathy under a mental disorder or neurological listing is medically inappropriate. Hepatic encephalopathy occurs primarily in patients with decompensated liver failure, but can also occur in patients with seemingly mild liver disease. In whatever setting in which it occurs, hepatic encephalopathy is a serious and uniformly debilitating condition. From a medical standpoint, it is far more logical and appropriate for the issue of hepatic

encephalopathy to be addressed in the evaluation criteria for chronic liver disease than to be addressed as a mental or neurological disorder.

F. *What are our guidelines for evaluating specific digestive impairments?*

2. Chronic liver disease is liver cell necrosis, inflammation, **and/or** scarring from any cause that persists for more than 6 months, and is expected to continue for at least 12 months **or the remainder of an individual's natural life**. Clinical manifestations may vary from an asymptomatic state to incapacitation due to liver failure. Acute hepatic injury **may be wholly or partially reversible as in drug-induced hepatitis, hepatitis A, acute hepatitis B, alcohol-induced hepatitis, and acute hepatic ischemia**. In the absence of continuing evidence of a chronic impairment, episodes of acute liver disease do not necessarily meet the requirement for chronic liver disease.

(a) Signs and symptoms of chronic liver disease **may include one or more of the following: chronic fatigue, impaired cognitive function (poor concentration, memory, and/or analytical thinking), jaundice (yellow appearance of the skin and mucous membranes), intractable pruritis (itching), ascites (accumulation of fluid in the abdominal cavity), lower or upper extremity edema (swelling due to accumulation of fluid in the tissues), gastrointestinal bleeding, nausea, chronic indigestion, diarrhea or constipation, bloating, loss of appetite, sleep disturbances, mood disturbances, weakness, musculoskeletal pain, and abdominal pain**. Laboratory findings in cases involving liver disease may include **but are not limited to increased liver enzymes, decreased serum albumin, increased serum bilirubin, abnormal coagulation studies, decreased platelets, acid-base imbalances, serologic and/or confirmatory tests indicating chronic hepatic viral infection, and abnormal liver biopsy**.

(b) Liver disease may result in portal hypertension, **gastrointestinal varices, ascites, decreased cognitive function, hepatic encephalopathy, coagulation disorders, vitamin deficiencies and complications thereof, malnutrition, abnormal fat, protein, and carbohydrate metabolism, anemia, hepatorenal syndrome, hepatopulmonary syndrome, and/or liver transplantation**. [OMIT: We should assess impairment due to hepatic encephalopathy under the criteria for the appropriate mental disorder or neurological listing.

NOTE: As stated earlier, we recommend that hepatic encephalopathy is most appropriately assessed under chronic liver disease, not as a mental or neurological disorder.]

(c) **Hemorrhage from gastroesophageal varices typically involves hematemesis (vomiting of blood), melena (passage of dark stools containing blood), and/or hematochezia (passage of bloody stools). Hemorrhage from other gastrointestinal hemorrhages beyond the stomach typically involve melena and/or hematochezia. A gastrointestinal hemorrhage may cause you to become hemodynamically unstable as shown by signs and symptoms such as pallor (paleness), diaphoresis (profuse perspiration), rapid heart rate, low blood**

pressure, postural hypotension (fall in blood pressure when standing), and syncope (fainting). A massive hemorrhage can be life-threatening with an urgent need for transfusion, fluid replacement, and other supportive care.

(d) Liver tests [NOTE: liver enzymes are not liver function tests] such as enzyme levels do not necessarily correlate with the severity of liver disease present, and must not be relied upon in isolation. Ascites, when associated with either albumin depletion or prolongation of the prothrombin time, usually indicates severe loss of liver function. Small volume ascites, as might be detected only by imaging techniques, that is not associated with albumin depletion, prolongation of the INR (prothrombin time), or other manifestations of chronic liver disease may be an incidental and clinically insignificant finding. Such a finding in isolation is not sufficient to meet the criteria in listing 5.05B. Other factors must be considered.

NOTE: Additional language we recommend adding to the #2 entry is noted below. The placement would be most logical between current paragraphs (d) and (e).

Portal hypertension secondary to chronic liver disease usually indicates severe loss of liver function. Likewise, hepatorenal and hepatopulmonary syndromes, and hepatic encephalopathy are severe conditions associated with substantial liver and functional impairment. Extrahepatic manifestations of chronic liver disease such as coagulation disorders, impaired glucose metabolism, syndromes associated with cryoglobulinemia, intractable pruritis, spontaneous peritonitis, and documented cognitive impairments may cause substantial loss of physical and functional capacity. Comorbid liver conditions, and other comorbidities such as concurrent HIV disease, pulmonary disease, cardiovascular disease, and addiction disorders typically exacerbate the signs, symptoms, and functional impairments associated with chronic liver disease.

(e) Liver transplantation may be performed for progressive liver failure, life-threatening complications of liver disease, tumor, or trauma. Placement on a liver transplant waiting list indicates severe loss of liver function. Disability is considered to last from the time of placement on a liver transplant list to one year from the date of transplant. After that time, we will evaluate the residual impairment(s), as outlined in paragraph (g) below.

(f) [No comments or recommendations on the proposed changes.]

(g) [No comments or recommendations on the proposed changes.]

Proposed Listings: Chronic Liver Disease, Adult Criteria

5.05 Chronic liver disease of any kind, WITH:

NOTE: We strongly recommend that “and cirrhosis” be omitted from listing 5.05 because there are a number of legitimate cases of significant impairment caused by chronic liver disease that may not have histologically progressed to cirrhosis. This listing should not be limited based on a histologic finding since the issue at hand is determination of functional impairment, and histological findings may not correlate with functional capacity.

A. Bleeding caused by portal hypertension including but not limited to gastroesophageal variceal bleeds demonstrated by x-ray, endoscopy, or other appropriate medically acceptable imaging or testing and requiring transfusion or other hemodynamic stabilization measures.

NOTE: The stated requirement of 5 units of blood in 48 hours is not medically appropriate. Any bleed occurring as a complication of portal hypertension, including esophageal or gastric varices, portal hypertensive gastropathy, colonic or small bowel varices, or portal hypertensive gastropathy that requires transfusion and/or hemodynamic stabilization measures is clinically significant and indicates significant underlying disease. Consider under a disability for 1 year following the last documented hemorrhage requiring hemodynamic intervention; thereafter, evaluate the residual impairment(s); OR

B. Ascites persisting over a consecutive 3-month period despite prescribed treatment as documented by:

NOTE: The requirement for 6-months duration of ascites in the setting of chronic liver disease is excessive; people with liver disease that is severe enough to cause persistent, clinically significant ascites for 3 months duration despite treatment undeniably have severe liver disease. Further, the requirement for findings to be demonstrated on “at least two evaluations occurring at least 2 month apart within the 6-month period” seems arbitrary, and excessively onerous in light of the known natural history of chronic liver disease and associated ascites.

1. Ascites documented by paracentesis; OR

2. Ascites documented on physical examination and by appropriate medically acceptable imaging with:

(a) an associated decrease in serum albumin; OR

NOTE: The actual value is dependent upon numerous factors including the degree of portal hypertension, hydration status, and whether an underlying malignancy is present; setting a cut-off level is therefore inappropriate.

(b) prolongation of the INR (prothrombin time); OR

NOTE: A cut off of at least 2 seconds is both arbitrary and medically questionable; a person with chronic liver disease that has resulted in a coagulation disorder has severe disease, regardless of whether the

prolongation is 1.5 or 2 seconds. Further, many laboratories no longer report PT results in terms of seconds, but rather report the INR.

(c) an underlying hepatic malignancy; OR

(d) documented portal hypertension.

We strongly recommend the following criteria be added to the 5.05 listing to help evaluators more easily identify those with severe chronic liver disease at the listing level. This will save SSA time and money in terms of evaluation, and will help insure a timely decision for those in need of assistance. Our recommendations would make the evaluation of chronic liver disease more on par with the evaluation of human immunodeficiency virus infection (14.08). We believe this is appropriate since both HIV disease and chronic hepatitis C are systemic illnesses that encompass a broad spectrum of disease and potential impairment with many constitutional and systemic signs and symptoms.

C. Hepatopulmonary syndrome persisting for a period of 2 months despite prescribed therapy; OR

D. Hepatorenal syndrome; OR

NOTE: These patients are critically ill; anyone carrying this diagnosis regardless of duration is suffering grave debilitation.

E. Hepatic encephalopathy persisting for a period of 30 days despite prescribed therapy; OR

F. Diagnosis of hepatocellular carcinoma as documented by liver biopsy or imaging according the United Network for Organ Sharing guidelines; OR

G. Placement on a liver transplantation waiting list; OR

H. Symptomatic cryoglobulinemia documented by clinical laboratory testing with one or more of the following manifestations persisting for 3 months despite prescribed therapy:

- 1. membranoproliferative glomerulonephritis**
- 2. peripheral neuropathy**
- 3. arthritic symptoms mimicking rheumatoid arthritis; OR**

I. Extrahepatic HCV-related syndromes persisting for 3 months despite prescribed therapy, including but not limited to:

- 1. Sjögren's syndrome**
- 2. Sicca syndrome**
- 3. porphyria cutanea tarda**
- 4. polyarteritis nodosum**
- 5. peripheral neuropathy; OR**

J. Malabsorption with involuntary weight loss of 10% or more of baseline and in the absence of a comorbid condition that could explain the findings; OR

K. Intractable pruritis persisting over a period of 3 months despite prescribed treatment and the exclusion of other potentially treatable causes; OR

L. Persistent manifestations of chronic liver disease including those listed in 5.05 A-K but without the requisite findings, or other manifestations resulting in significant, documented signs and/or symptoms including decreased cognitive function, decreased memory acuity, fatigue, weakness, fever, malaise, lethargy, weight loss, abdominal pain, appetite disturbance, mood disturbance, and insomnia, and one of the following at the marked level:

- 1. restriction of activities of daily living; or**
- 2. difficulties in maintaining social functioning; or**
- 3. difficulties in completing tasks in a timely manner due to deficiencies in concentration, persistence, or pace.**

IV. SECOND PATH: TREATMENT AS AN OPTION FOR APPLICANTS WITH CHRONIC HEPATITIS C

During the SSA Policy Conference on Chronic Liver Disease, a most interesting idea was raised by Mr. Martin H. Gerry, Deputy Commissioner of the Office of Income Security Programs. His idea involved making a determination whether an applicant with chronic hepatitis is a candidate for potentially curative therapy during the course of his or her medical evaluation, and offering treatment to eligible candidates. We enthusiastically support and recommend the adoption and implementation of this approach.

One of the most difficult issues in battling the hepatitis C crisis is the fact that the vast majority of those infected are unaware that they have the virus until they begin to show signs of advanced liver disease, a development that may not occur until 10-20 years after infection. However, even after long-standing infection, state-of-the-art treatment with pegylated interferon plus ribavirin offers the hope of viral cure to approximately 50% of those treated. Recent evidence suggests that curative therapy not only halts disease progression, but may lead to partial recovery of sustained liver damage. Furthermore, some evidence suggests that even among those who are treated but not cured of the virus, interferon-based therapy may slow disease progression and reduce the risk of developing liver cancer.^{19, 20, 21, 22, 23}

Unlike HIV and most other viral illnesses including the common cold, we have a treatment available to potentially cure chronic hepatitis C. Further, hepatitis C treatment is limited in duration (24-48 weeks). Seizing the opportunity to intervene in chronic hepatitis C before potentially devastating sequelae such as liver failure and/or liver cancer develop is not only ethically paramount, it is also fiscally beneficial. The cost of 24-48 weeks of interferon-based therapy is negligible compared to the cost of life-long disability and medical care for someone with progressive liver disease that may eventually require liver transplantation.

On December 14, 2004, the House Committee on Government Reform conducted an oversight hearing entitled, “Stalking a Furtive Killer: A Review of the Federal Government’s Efforts to Combat Hepatitis C.” The hearing concluded with all members of the Committee in attendance agreeing that federal efforts to date to intervene in the hepatitis C epidemic are lacking. Implementation of a second path, i.e., treatment for eligible candidates with chronic hepatitis C applying for Social Security disability is a unique opportunity to make significant strides in this crisis among the uninsured and underinsured. From all perspectives – fiscal, social, personal, and ethical – this second path option is not only feasible, but advantageous. With the utmost urgency, we recommend that SSA begin work to develop an implementation strategy for this second path option.

RECOMMENDATION 6

Develop and implement a strategy to offer uninsured or underinsured, medically-eligible applicants with chronic hepatitis C curative-intent treatment for their disease.

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